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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/256,156    02/24/99    GILLIES

S    LEX-003

021323  
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HM12/0829

EXAMINER

MURPHY, J

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

08/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/256,156

Applicant(s)

GILLIES ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 14-24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

#### ***Election/Restrictions***

2. Applicant's election of Group I, claims 1-13 and 25 in Paper No. 11, 6/12/2000 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 14-24 and 26 are withdrawn from further consideration by the examiner as being drawn to a non-elected invention, 37 CFR 1.142(b).

3. Claims 1-13 and 25 are under consideration.

#### ***Claim Objections***

4. Claim 25 is objected to because of its dependence on a non-elected claim. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112 second paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-13 are rejected insofar as they depend on the recitation of the term "substantially".

Claim 5 is vague and indefinite in the recitation of the term "immunoglobulin protection receptor". There is nothing in the claims which distinctly identifies the protein. For example, others in the field may isolate the same protein and give said protein an entirely different name. Applicant should particularly point out and distinctly identify the polypeptide by claiming structural characteristics associated with the protein (e.g. amino acid sequence, molecular weight, etc.). Identification of biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly designate what that protein is.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 1, 3, 6-9, 13 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoogenboom et al. (1991).

Hoogenboom et al. teaches the design and production of two antibody-TNF fusion proteins (page 1031, Figure 1 and page 1032, Figure 2). In one antibody-TNF fusion construct, the human TNF gene is linked to the CH2 domain of the human gamma-1 chain. In this construct Leu-235 was deleted, thus decreasing binding of the antibody-TNF fusion protein to Fc receptors (page 1029, column 2, second paragraph). Thus, the limitations of claims 1, 3, 6-9, 13 and 25 are met.

6b. Claims 1, 4, 7-8, 10- 13 rejected under 35 U.S.C. 102(a) as being anticipated by WO 97/30089.

WO 97/30089 discloses the construction, synthesis and expression of an IL-2/antibody fusion protein (page 9, first paragraph). This fusion protein has the N-terminus of human IL-2 fused to the C-terminus of IgG3, including the CH2 domain (page 10, third paragraph). This IL-2/antibody fusion protein has an increased half-life (page 10, fourth paragraph). WO 97/30089 also discloses that the antibody may be fused to a lymphokine including, *inter alia*, GM-CSF (page 6, paragraph 2). Thus meeting the limitations of claims 1, 4, 7-8, 10-13.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoogenboom et al. (1991), in view of U.S. Patent No. 6,100,387.

The teaching of Hoogenboom et al. has been set forth in section (6a), above.

Hoogenboom et al. does not disclose an antibody based-fusion protein which comprises the CH2 domain of an IgG4 constant region. U.S. Patent No. 6,100,387 (column 20, lines 22-25) discloses the construction and expression of a chemokine-encoding fragment, a fragment containing a linker and part of the Fc portion of the IgG4 gene, a fragment containing the rest of the Fc portion of the IgG4 gene, and a vector fragment. The Fc region of this chimeric gene encodes a protein which is comprised of the hinge, CH2, and CH3 regions of human IgG4. Therefore, it would have been obvious to one of skill in the art at the time the invention was made to produce an antibody-based fusion protein with an Fc region comprising the CH2 domain of IgG4. The motivation is provided in U.S. Patent No. 6,100,387 (column 24, Table 2 and 3) which shows the success of these antibody-based fusion polypeptides to bind to receptors expressed by several human cell lines.

***Conclusion***

No claim is allowed.

Art Unit: 1646

*Advisory Information*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
August 24, 2000

  
PREMA MERTZ  
PRIMARY EXAMINER